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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/751,299 | 12/28/2000 | Mark Madden | DIVER1440-2 | 8629 |
| 25225 | 7590 | 06/30/2005 | EXAMINER | |
| MORRISON & FOERSTER LLP 3811 VALLEY CENTRE DRIVE SUITE 500 SAN DIEGO, CA 92130-2332 | | | KERR, KATHLEEN M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1656 | |

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,299

Applicant(s)

MADDEN ET AL.

Examiner

Kathleen M. Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,32,36,37,44 and 49-65 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 31,32,36,37,44,49,50,52 and 54-61 is/are rejected.
7) ☒ Claim(s) 51,53 and 62-65 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/23/05
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on November 26, 2004), Applicants filed a response and amendment received on April 11, 2005. Said amendment cancelled Claims 1-8, 10-21, 23-30, 33-35, 38-43, and 45-48 and amended Claims 31, 32, 36, 37, 44, and 49-50 and added new Claims 51-65. Thus, Claims 31, 32, 36, 37, 44, and 49-65 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application Nos. 60/173,609 and 60/254,414 filed on December 29, 1999 and December 7, 2000, respectively.

Information Disclosure Statement

3. The information disclosure statement filed on March 23, 2005 has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copies.

Change of Inventorship/New Declaration

4. In view of the papers filed February 14, 2005, it has been found that this non-provisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 C.F.R.

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§ 1.48(a). The inventorship of this application has been changed by addition of Dan E. Robertson.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Withdrawn - Objections to the Specification

5. Previous objection to the amendment filed July 22, 2003 under 35 U.S.C. § 132 because it introduces new matter into the disclosure is withdrawn by virtue of Applicant's amendment removing the identification of enzymes BD 1911 and BD 1912 in Example 1 as SEQ ID NOs: 2 and 4.

Withdrawn - Objections to the Claims

6. Previous objection to Claim 1 for improper punctuation is withdrawn by virtue of Applicant's cancellation of said claim.

7. Previous objection to Claim 23 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicant's cancellation of said claim.

New - Objections to the Claims

8. Claims 51, 53, and 62-65 are objected to for depending from rejected claims.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

9. Previous rejection of Claims 1-8, 10, 23, 24, 38-43, 45-46, and 49-50 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “reaction components” is withdrawn by virtue of Applicant’s amendment defining said components.
10. Previous rejection of Claims 44 and 50 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “the same enzymatic activity as nucleic acid sequence from which it varies” is withdrawn by virtue of Applicant’s amendment.
11. Previous rejection of Claims 1-8, 10-17, 23, 24, 33, 38-43, and 45-48 under 35 U.S.C. § 112, first paragraph, enablement, for method producing enantiomerically pure α -substituted carboxylic acids is withdrawn by virtue of Applicant’s cancellation of said claims.
12. Previous rejection of Claims 34-35 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for methods using SEQ ID NOs: 2 or 4 to stereoselectively (>50% ee) produce (S)-phenylglycine from phenylglycinonitrile (or benzaldehyde, KCN, and NH_4Cl), does not reasonably provide enablement for methods producing any α -substituted carboxylic acid is withdrawn by virtue of Applicant’s cancellation of said claims.
13. Previous rejection of Claims 24, 38-43, 46, and 48 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for methods using SEQ ID NOs: 2 or 4 to stereoselectively (>50% ee) produce (S)-phenylglycine from phenylglycinonitrile (or benzaldehyde, KCN, and NH_4Cl), does not reasonably provide

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enablement for methods producing using sequences related to SEQ ID NOs: 2 or 4 with as little as 70% identity is withdrawn by virtue of Applicant's cancellation of said claims.

Maintained - Claim Rejections - 35 U.S.C. § 112

14. Previous rejection of Claims 31-32, 36-37, 44, 49, and 50 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for methods using SEQ ID NOs: 2 or 4 to stereoselectively (>50% ee) produce (S)-phenylglycine from phenylglycinonitrile (or benzaldehyde, KCN, and NH_4Cl), does not reasonably provide enablement for methods producing any α -substituted carboxylic acid is maintained. Moreover, new Claims 52, 54-61 are added to the instant rejection. Thus, Claims 31-32, 36-37, 44, 49, 50, 52, and 54-61 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.

Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that nitrilase substrates are easily identified. This idea is attested to in the declaration provided. The declaration under 37 C.F.R. § 1.132 filed on April 11, 2005 is insufficient to overcome the instant rejection because the idea that nitrilase substrates is insufficient to overcome the instant rejection. As previously noted, "the predictability of the substrate specificity of SEQ ID NOs: 2 and 4 is very low considering the little information disclosed in the instant specification and the prior art." Moreover, the declaration and Applicant's other arguments of record discuss how numerous nitrilases (137) were screened quickly with two prototypical substrates easily, thus, only two substrates and not the virtually boundless number of substrates are encompassed by the claimed scope of the instant methods. The Examiner notes the exclusion of Claim 51 from the instant rejection since limiting the

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produced substituted carboxylic acid has the effect of limiting the aldehyde or ketone substrates that can be used.

The Examiner further notes that for independent Claims 31, 36, 44, 49, and 50, the preamble describes producing alpha-substituted (with any substitution) carboxylic acids while the method steps make *only* alpha-amino acids (substituted with an amino group) by virtue of using the ammonia compounds (which interact with the aldehyde or ketone to produce an amino nitrile). Thus, enabling the production of compounds other than alpha-amino acids in these claims is not taught by the disclosure. For independent Claim 32, only alpha-hydroxy-substituted carboxylic acids and alpha-amino acids are produced by starting with a cyanohydrin or an amino nitrile, respectively. Thus, enabling the production of compounds other than alpha-hydroxy-substituted carboxylic acids and alpha-amino acids in these claims is not taught by the disclosure.

15. Previous rejection of Claims 44 and 50 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for methods using SEQ ID NOs: 2 or 4 to stereoselectively (>50% ee) produce (S)-phenylglycine from phenylglycinonitrile (or benzaldehyde, KCN, and NH₄Cl), does not reasonably provide enablement for methods producing using sequences related to SEQ ID NOs: 2 or 4 with as little as 70% identity is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues points of written description; however, no written description rejection under 35 U.S.C. § 112, first paragraph, was set forth in the previous Office action.

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Applicant also argues that the specification provides enough guidance for one of skill in the art to identify sequences within the structural limitation and then to identify which of those retain functional activity as required. While the Examiner agrees that one of skill in the art could randomly mutate and screen for activity, this ability to find the invention (within the claimed scope) is not an ability to make the invention as required and as previously noted. As previously noted,

“The only specific description in the instant application of the enzymes of SEQ ID NOs: 2 and 4 is their polypeptide sequences (see Sequence Listing) and their activity on phenylglycinonitrile (see Example 1). No description of how their sequences reflect the nitrilase activity they have. The prior art is relatively silent on the generic structure of nitrilases. Thus, the ability to vary the sequences disclosed and maintain nitrilase activity, in particular stereoselective nitrilase activity, is unpredictable. While the instant specification describes and enables means for identifying other nitrilase genes encoding polypeptides similar to SEQ ID NOs: 2 and 4 using hybridization methods, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the polypeptides used in the methods within the scope of the claims because **the ability to find** other nitrilases, which is structurally related to SEQ ID NOs: 2 or 4, **is not equivalent to the ability to make** other nitrilases as required by the statute (i.e., “make and use”). No description in the specification or the art provides particular residues whose encoding is important within the disclosed sequence so that its nitrilase-nature is maintained. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members. Therefore, the instant claims are not enabled to the full extent of their scope.” (emphasis added)

Summary of Pending Issues

16. The following is a summary of the issues pending in the instant application:

- a) Claims 31-32, 36-37, 44, 49, 50, 52, and 54-61 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
- b) Claims 44 and 50 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for methods using SEQ ID NOs: 2 or 4 to stereoselectively (>50% ee) produce (S)-phenylglycine from phenylglycinonitrile (or benzaldehyde, KCN, and NH_4Cl), does not reasonably provide enablement for methods producing using sequences related to SEQ ID NOs: 2 or 4 with as little as 70% identity.

- c) Claims 51, 53, and 62-65 stand objected to for depending from rejected claims.

Conclusion

17. Claims 51, 53, and 62-65 are objected to; Claims 31, 32, 36, 37, 44, 49, 50, 52, and 54-61 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

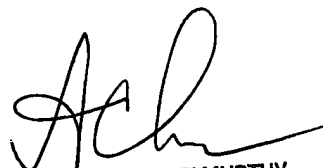
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M. Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600



Kathleen M Kerr
Primary Examiner
Art Unit 1652

June 16, 2005